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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,166	03/05/2002	David A. Adler	97-44D1	7711

7590 01/09/2007

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/091,166	ADLER ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,21-25,45,46 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-5,21-24,45,46 and 50* is/are allowed.

6)☒ Claim(s) *25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-5, 21-25, 45, 46 and 50 are pending.

Applicants' amendments filed June 3, 2005 is acknowledged. Applicants' response has been fully considered. Claims 26, 28, 29, 37, 38, 40-44 and 47-49 have been cancelled. Therefore, claims 1-5, 21-25, 45, 46 and 50 are examined.

Withdrawn Informalities

2. The previous objection to the specification regarding hyperlink and trademarks, is withdrawn in view of applicants' amendment to the specification, and applicants' response at page 8 in the amendment filed June 3, 2005.

Withdrawn Objection to Specification

3. The previous objection to the specification regarding the new matter is withdrawn in view of applicants' cancellation of claims 26, 28, 29, 37, 38 and 40-43, and applicants' response at page 8 in the amendment filed June 3, 2005.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 26, 28, 29, 37, 38 and 40-43 under 35 U.S.C. 112, first paragraph, regarding new matter, is withdrawn in view of applicants' cancellation the claim, and applicants response at page 9 in the amendment filed June 3, 2005.

5. The previous rejection of claims 1-2, 4, 44 and 47-49 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in view of applicants' cancellation the claim, and applicants response at pages 9-10 in the amendment filed June 3, 2005.

6. The previous rejection of claim 44 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' cancellation the claim, and applicants response at page 10 in the amendment filed June 3, 2005.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

7. The previous rejection of claim 50 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 64 of co-pending application 10/409,366 is withdrawn in view of applicants' abandonment of 10/409,366, and applicants' response at page 10 in the response filed June 3, 2005.

8. The previous rejection of claims 1-5, 21-26, 28-29, 37-38 and 40-50 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-43 and 45-90 of co-pending application 10/272,121 is withdrawn in view of applicants' abandonment of 10/272,121, and applicants' response at page 10 in the response filed June 3, 2005.

9. The previous rejection of claims 1-5, 21-26, 28-29, 37-38 and 40-50 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-65 of co-pending application 10/409,366 is withdrawn in view of applicants' abandonment of 10/409,366, and applicants' response at page 11 in the response filed June 3, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 25 is directed to a method of contraception in a mammal comprising administering to the mammal a therapeutically effective amount of a polypeptide of the amino acid residues 1-67, 21-67, 23-67, 20-67 or 22-67 of SEQ ID NO:10 or a polypeptide of the amino acid residues 30-63, 31-63, 30-64 or 31-64 of SEQ ID NO:2. The specification, however, only discloses cursory conclusions without data supporting the findings, which state the present invention provides a method of contraception by administering a therapeutically effective amount of the polypeptides of the present invention to a mammal, and such administration would be useful in preventing implantation and/or development of the embryo (page 24, line 1-5). There are no indicia that the present application enables the full scope of the claims in view of the method of contraception as discussed in the stated rejection. The present application does not provide sufficient teaching/guidance to enable the full scope of the claims. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breadth of the claims, the presence or absence of working examples, the state of the prior art and relative skill of those in the art, the predictability or unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breadth of the claims:

The breadth of the claims encompasses the use of a therapeutically effective amount of a polypeptide of the amino acid sequence of SEQ ID NO:10 or specific fragments of SEQ ID NO:10 or 2 in contraception, which is not adequately described or demonstrated in the specification.

(2). The presence or absence of working examples:

There is no working example indicating the use of these peptides in contraception.

(3). The state of the prior art and relative skill of those in the art:

The related art (e.g., Sawicki et al., lancet 353, 464-465 (1999)) teaches the in vitro cytotoxicity of β-defensin (hBD-2) and magainin-2-amide for mouse oocytes and preimplantation embryos. However, the general knowledge and level of the skill in the art do not supplement the omitted description, e.g., the in vivo use of the amino acid sequence of SEQ ID NO:10 or specific fragments of SEQ ID NO:10 or 2 in contraception. The specification needs to provide specific guidance on the treating conditions such as effective amounts of the polypeptides to be considered enabling in the claimed methods.

(4). Predictability or unpredictability of the art:

The claims encompass a method of contraception in a mammal comprising administering to the mammal a therapeutically effective amount of a polypeptide of SEQ ID NO:10 or specific fragments of SEQ ID NO:10 or 2. While the in vitro cytotoxicity of β-defensin (hBD-2) and magainin-2-amide for mouse oocytes and preimplantation embryos was shown in the art, the specification does not teach how to use the claimed polypeptides either in vitro or in vivo treatment, the invention is unpredictable regarding the treating conditions and the effects of the polypeptides in the contraception.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

Claim 25 is directed to a method of contraception in a mammal comprising administering to the mammal a therapeutically effective amount of a polypeptide of SEQ ID NO:10 or specific fragments of SEQ ID NO:10 or 2. While the specification indicates the present invention provides a method of contraception by administering a therapeutically effective amount of the polypeptides of the present invention to a mammal, and such administration would be useful in preventing implantation and/or development of the embryo (page 24, line 1-5), the specification does not describe the use of the claimed polypeptides for in vitro or in vivo treatment in contraception. Moreover, there are no working examples demonstrating the claimed method. Since the specification does not provide sufficient teachings on the use of the polypeptide of SEQ ID NO:10 or specific fragments of SEQ ID NO:10 or 2 in contraception , it is necessary to carry out undue experimentation to find proper treating conditions such as effective dose in the treatment.

(6). Nature of the Invention

The claims encompasses the use of the polypeptide of SEQ ID NO:10 or specific fragments of SEQ ID NO:10 or 2 in contraception in a mammal, but the specification does not provide sufficient teachings in the use of the peptide either in vitro or in vivo treatment. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, there are no working examples demonstrating the claimed methods, the treating conditions are not taught in the specification, and the effect of the polypeptide in

contraception is unpredictable, therefore, it is necessary to carry out undue experimentation to practice the claimed methods.

Conclusions

11. Claim 25 is rejected; and it appears claims 1-5, 21-24, 45, 46 and 50 are free of art and allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

CHIH-MIN KAM
PRIMARY EXAMINER

CMK
January 4, 2007